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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,794	10/31/2003	Giovanni M. Pauletti	3715.17-1	1741

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EXAMINER	
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ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,794	PAULETTI ET AL.	
	Examiner	Art Unit	
	Charleswort Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/18/05; 2/9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response with traverse to the Restriction/Election requirements, filed 1/26/07, electing group II, film species, used for a coating of tampon-like device or tampon, using polyethylene oxide polymer, anti-inflammatory agent ketorolac, penetration enhancer and vaginal epithelium, is acknowledged and made of record. Applicant's statement that all pending claims are readable on the elected group and species is acknowledged.

Restriction/Election Requirement

Applicant's argument that if the device of the invention comprises a composition of the invention, then the composition including all its components should also be searched, as such search would discover prior art against group I and this would not place an undue burden on Examiner to examine both the device and composition claims, is not deemed persuasive for the reasons of record. Clearly, the device has acquired a different status in the art and is capable of being practiced with different compositions, while the compositions encompassed by the instant invention may be practiced without the device e.g. injectable or oral ingestion. Thus, a search of groups I and II would create an undue search burden.

Applicant's argument that both the film and foam are attached to the device of the invention and if the device of the invention is found patentable, both the film and foam species will also be found to be patentable, is deemed to be persuasive.

Applicant's statement is being construed as evidence of obviousness with respect to the film and foam species. The election requirement is therefore withdrawn.

Applicant's argument that polymers albeit they might be chemically different typically behave in the same way when they have the same function in the mucosal composition is deemed persuasive. Thus, the polymer species election requirement is hereby withdrawn.

Applicant's argument that when formulated as a composition, the therapeutically effective agents in all drug groups have the same or similar release properties is deemed persuasive. This election requirement is also withdrawn.

Applicant's argument that the epithelium tissue in all these organs or cavities in connection with the topical drug delivery sites is the same or similar and that the released drug formulated for a transmucosal delivery will be delivered through the mucosal tissue regardless where such mucosal tissue is located is deemed persuasive. Thus, the election requirement with respect to the topical drug delivery site species is hereby withdrawn.

Applicant's argument that to elect one element for search will also discover other components present in a composition (or subcomposition) is not deemed persuasive in view of the multiplicity of elements or ingredients encompassed by the instant invention and the reasons of record. This election of species requirement is maintained.

The Restriction/Election requirements are made final for the reasons stated above.

Status of the Claims

Claims 29-46 are currently pending in this application and are the subject of the Office action.

Claim rejections – 35 USC 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 USC 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

Claim 46 refers to the "[t]he composition of claim 45. To the extent that this claim is directed to a "composition," it lacks proper antecedent basis as claim 45 from which it depends is directed to a device. This claim is deemed to be indefinite because it fails to concisely define what applicant's deem as the invention.

For purposes of examination, claim 46 will be treated as a device.

Nonstatutory Obviousness-Type Double-Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 29-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-27 of US Patent 6,905,701 B2 ('701). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are either anticipated by, or would have been obvious in view of the referenced claims.

In particular, claim 24 of '701 is directed towards a medicated intraviginal device for a transmucosal delivery of bisphosphonates to the general circulation. In view of the fact that the treatment populations overlap, someone of skill in the art at the time the

instant invention was made would have deemed it obvious to create the instant invention with a reasonable expectation of success.

Thus, claims 29-46 are deemed obvious variants of the limitations of the patented subject matter claimed in '701.

For the same reasons stated above, claims 29-46 are similarly deemed to be obvious variants of the limitations of the patented subject matter of claims 21-33 of U.S. Patent 6,982,091 ('091).

In addition, claims 29-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the following: claims 49-54, 55, 57-79 of copending Application No. 10/335,759; claims 1-15 of copending Application No. 11/126,863, claims 45-53 of copending Application No. 11/208,209, claims 1-55 of copending Application No. 11/180,076, claims 1-14 of copending Application No. 10/654,145, and claims 20-23 of copending Application No. 11/522,126, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious variants of each other for essentially the same reasons stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims of the copending applications have not in fact been patented.

Claim rejections – 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29-46 are rejected under 35 USC 102(b) as being anticipated by Harrison et al. (US Patent 6,086,909).

Harrison et al. (6,086,909) teach devices, compositions and methods for treating dysmenorrheal by intravaginal administration of therapeutic and/or palliative drugs to the uterus (column 1, lines 13-16). Harrison et al. teach controlled release drug delivery system in the form of, for example, a tampon-like device, vaginal ring, pessary, tablet, paste, suppository, vaginal sponge, bioadhesive tablet, bioadheisve microparticles, cream, lotion, foam, ointment, or gel (column 9, lines 5-67). Harrison et al. teach various tampon like devices which can be used to deliver drugs for the treatment of dysmenorrheal wherein the drug is incorporated into the device via numerous methods (column 9, lines 29-34). Specifically, the drug can be incorporated into a gel-like bioadhesive reservoir in the tip of the device, or the drug can be in the form of a powdered material positioned at the tip of the tampon, or the drug can also be dissolved in a coating material which is applied to the tip of the tampon, or the drug can be incorporated into an insertable suppository which is placed in association with the tip of the tampon (column 9, lines 36-45). In Figure 6, the tampon device includes a distal porous foam section, which is preferably a soft, light weight, physiologically inert foam

material of polyurethane, polyester, polyether, or other material such as collagen (column 10, lines 28-40).

Harrison et al. invention is directed to the delivery of drugs to the uterus using medicated intrauterine tampon; the device allows delivery of the drug intravaginally in lower concentrations than those need for systemic treatment and thus provides for lower systemic concentration and fewer side effects (column 1, lines 16-21). In one aspect, the invention provides a method for treating a human female suffering from dysmenorrheal comprising contacting the vaginal epithelium of the female with a pharmaceutical agent selected from the group consisting of nonsteroidal anti-inflammatory drugs, anti-prostaglandins, prostaglandin inhibitors, COX-2 inhibitors, local anesthetics, calcium channel blockers, potassium channel blockers (column 1, line 66 to column 2, line 16). Harrison et al. teach that non-limiting examples of nonsteroidal anti-inflammatory drugs suitable for practice of the invention includes ketorolac (column 2, lines 17-21); see also Example 4 at columns 16-18).

Harrison et al. disclose methods for combining the pharmaceutical agent with a drug delivery system for intravaginal delivery of the agent; drug delivery system include a tampon device, vaginal ring, pessary, tablet, vaginal suppository, vaginal sponge, bioadhesive tablet, bioadhesive microparticle, cream, lotion, foam, ointment, solution and gel (column 2, second full paragraph). In one embodiment, a tampon device is sheathed in a thin, supple, non-porous material such as a plastic film or a coated gauze that surrounds the absorbent tampon material like a skirt and opens like an umbrella when it comes in contact with the vaginal environment (column 3, lines 55-67).

Harrison et al. teach a controlled release drug delivery system comprising non-limiting biocompatible excipient for applying the agent including a lipophilic carrier or a hydrophilic carrier e.g. polyethylene glycol; muco-adhesive agents such as alginate and pectin; and penetration enhancers e.g. bile salts, organic solvents, ethoxydiglycol, or interesterified stone oil (column 2, third full paragraph). In certain embodiments, the excipent comprises between about 60 to 90% by weight lipohilic carrier, between about 5 to 25% mucoadhesive agent, and between abut 5 to 20% penetration enhancer (column 2, lines 60-67). In another embodiment, the formulation comprise between about 5-20% sorption promoter (column 8, lines 31-34). Thus, the claimed invention is anticipated by Harrison et al. because the limitations of the instant invention overlaps with Harrison et al. for the reasons stated above.

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29-46 are rejected as being unpatentable over Harrison et al., in view of Yang (US Patent 6,316,019 B1), in view of Durrani (US Patent 6,159,491), in view of Pauletti et al. (US Patent 6,905,701).

The above discussion of Harrison et al. is herein incorporated by reference.

Yang (6,316,019 B1) teach a low temperature process for adding pharmaceutically active compounds to substrates, specifically substrates used in the manufacturer of disposable absorbent articles (column 2, lines 36-45). Claim 1 of the reference is directed towards a tampon prepared by preparing a solution of an olefinic diol and a pharmaceutically active compound , applying said solution to the disposable absorbent article (column 6). Yang discloses that liquid permeable material may be nonwoven fabric such as a spunbonded fabric, a thermal bonded fabric, a resin bonded fabric, and the like; a three-dimensional or two-dimensional apertured polymeric film; or any other suitable covering surface that is capable of allowing fluid to permeate and be comfortably worn against the perineum (column 5, line 62 to column 6, line 2). Yang teach that a non-limiting list of materials useful as the absorbent material includes cellulosic fibers; synthetic fibers; and superabosrobent polymers such as polyacrylic acid, and the like (column 6, lines 2-7). One of the meanings provided by The Compact Oxford English Dictionary for the word "film" is a "thin layer covering a surface (1 page). Given its broadest reasonable interpretation, the application of the olefinic diol

composition to the substrate i.e. tampon, would reasonably constitute a film coated tampon.

Durrani teach bioadhesive, prolonged release drug composition comprising a synergistic formulation of carrageenan, acrylic acid containing polymers, agarose and an effective amount of a therapeutic agent (column 6, line 10-13). Durrani disclose an embodiment containing acrylic containing polymer such as polycarbophil, a homopolymer such as acryclic acid and divinely glycol, a copolymer of acrylic acid and a selected C10 to C30 alkyl acrylate copolymer (column 6, lines 19-26). Durrani teaches that one or more of the therapeutic agents dispersed or dissolved within the bioadhesive, prolonged release dreug composition may be selected from drugs, including, for example, antiinflammtory, antineoplastic or an analgesic agent. Durrini discloses a bioadhesive vaginal gel dosage form designed to incorporate a therapeutic agent for local or systemic action when administered intravaginally.

Pauletti et al (US Patent 6,905,701 B2) teach improved formulations for transmucosal vaginal delivery of bisphosphonates comprising from about 0.01 to about 3200 mg of a selected bisphosphonate, from about 0.01 to about 55 hydroxypropyl methylcellulose, from about 40 to about 95% of a selected saturated monoglyceride, diglyceride or triglyceride fatty acids, from about 5 to about 25 % of ethoxydiglycol and, optionally, other pharmaceuticaly acceptable excipients and additives (column 1, lines 19-32). Pauletti et al. disclose that the formulation is prepared as a vaginal suppository, tablet, bioadhesive tablet, capsule, micorparticle bioadhesive microparticle, cream, lotion, foam, film, ointment, solution etc. (column 3, lines 47-54). Pauletti et al. disclose

vaginal devices, such as a tampon, tampon-like device, pessary, ring, sponge, strip or cup incorporated woth an improved transmucosal vaginal formulation suitable for delivery of bisphosphonates to the systemic circulation (column 3, lines 54-64). Pauletti et al. disclose a tampon drug delivery system in a dehydrated sheathe state (column 5, lines 44-46). Pauletti et al disclose bioadhesive particulate delivery systems consisting of polymers and combinations thereof; it is disclosed that many of these systems were designed for nasal use, but can be easily modified for use in the vagina (column 19, lines 62-65).

In view of the teaching of Pauletti et al. of the improved transmucosal formulations for vaginal drug delivery, someone of skill in the art would have been motivated to combine the teachings of Harrison et al., and Yang, and Durrani, and Pauletti et al. to create an device for improved transmucosal drug delivery. Thus, someone of skill in the art at the time the instant invention was made would have deemed it obvious to create the instant claimed invention with a reasonable expectation of success in view of Yang, in view of Durrani, and further in view of Pauletti et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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12 April 2007
CER

BRIAN-YONG S. KWON
PRIMARY EXAMINER